<Date>

Cyanokit (hydroxocobalamin) 5 g powder for solution for infusion: Quality defect due to potential microbial contamination of certain batches resulting in a potential risk of infection

Dear Healthcare Professional,

The marketing authorisation holder SERB SA in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following:

Summary

- **The manufacturing of Cyanokit has been suspended due to the investigation of an ongoing quality defect. This has resulted in a shortage of the product in the European Union.**
- **The quality defect involves a potential risk of microbial contamination of certain batches (see below), which could compromise their sterility and lead to a potential risk of infection in patients receiving Cyanokit.**
- **While the risk of contamination in these batches cannot be totally excluded, it is considered minimal and outweighed by the benefit of using Cyanokit in cases of acute suspected cyanide intoxication.**
- **Healthcare professionals likely to use impacted batches should ensure that:**
    - **Cyanokit is reserved for patients presenting with clinical signs of acute intoxication in a context suggestive of exposure to cyanide such as inhalation of fire smoke or ingestion of a cyanide salt or cyanogenic product.**
    - **These include cardiac arrest, shock, respiratory distress, coma, high lactic acidaemia (>8 mmol/L). Cyanokit should not be used in the absence of signs of hypoxia. If systemic infection or sepsis is suspected (e.g., fever, persistent hypotension indicative of shock), initiate blood cultures and start empiric antibiotic therapy, adjusting based on pathogen identification and susceptibility results.**

Background on the safety concern

Cyanokit is indicated for the treatment of known or suspected cyanide poisoning in all age ranges. Cyanokit is to be administered together with appropriate decontamination and supportive measures.

The batches of Cyanokit listed in the table below were manufactured during the period affected by this quality defect and are therefore potentially impacted.

Batch number	Expiry date	List of Member States where potentially impacted batch was/will be distributed
2404	25-Jan-2027	• Austria • Belgium • Bulgaria • Croatia • Cyprus • Czechia • Denmark • Estonia • Finland • Germany • Greece • Hungary • Iceland • Ireland • Northern Ireland • Italy • Latvia • Lichtenstein • Lithuania • Luxembourg • Malta • Netherlands • Norway • Poland • Portugal • Romania • Slovenia • Spain • Sweden
2406	7-Feb-2027	• France
2408	25-Mar-2027	• France
2409	2-Apr-2027	• France
2411A	31-Mar-2027	• Austria • Belgium • Bulgaria • Croatia • Cyprus • Denmark • Estonia • Finland • France • Germany • Greece • Iceland • Ireland • Northern Ireland • Italy • Latvia • Lichtenstein • Lithuania • Luxembourg • Malta • Netherlands • Norway • Romania • Slovenia

		• Spain • Sweden
2412	31-Mar-2027	• Austria • Belgium • Germany • Greece • Cyprus • France • Ireland • Northern Ireland • Italy • Lichtenstein • Luxembourg • Malta • Netherlands • Romania
2413	30-Oct-2026	• France
2417	19-Jun-2027	• Austria • Belgium • Germany • Greece • Cyprus • Ireland • Northern Ireland • Italy • Lichtenstein • Luxembourg • Malta • Netherlands • Romania
2419V	03-Jul-2027	To be determined.

All these batches met the registered specifications for release, including sterility and endotoxin tests. No deviations linked to the quality defect were identified during their manufacture.

SERB Pharmaceuticals conducted a risk assessment, which demonstrates that it is not possible to eliminate all the sterility assurance risks for the affected batches. However, based on a detailed batch-by-batch assessment, it was concluded that the benefit of the product to patients outweigh the potential risks associated with the quality defect.

The decision was reached as the risk to patients from non-availability of Cyanokit, which is considered critical in multiple Member States, is considered a greater risk to public health than the risk associated with making these batches available.

No safety signals related to this quality defect have been reported at this stage. SERB Pharmaceuticals will continue to monitor the risk through pharmacovigilance data including adverse event reporting, customer complaint and medical information processes.

Due to the time needed to implement corrective and preventive actions, normal manufacturing of Cyanokit will not be able to resume for several weeks.

Call for reporting

Healthcare Professionals should report any adverse reactions suspected of being due to Cyanokit to SERB Pharmaceuticals:

- Postal address: SERB SA, Avenue Louise 480, 1050 Brussels (Belgium)
- Email: safety@serb.com
- Phone: +33 1 73 03 20 00
- Fax: +33 1 78 76 99 43

Healthcare Professionals should report any product complaints or adverse events suspected to be associated with the use of Cyanokit® 5 g powder for solution for infusion through their spontaneous national reporting system.

Company contact point

If you have any questions, please contact SERB Pharmaceuticals Quality Department at quality@serb.eu. If you require further medical information, please contact SERB Pharmaceuticals Medical Information Department**:**

- Email: infomed@serb.eu
- Phone: +33 1 73 03 20 00
- Website : www.serb.com

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Cyanokit (hydroxocobalamin) 5 g powder for solution for infusion
Marketing authorisation holder(s)	SERB S.A.
Safety concern and purpose of the communication	Quality defect due to potential microbial contamination of certain batches resulting in a potential risk of infection.
DHPC recipients	Intensive Care Unit and emergency specialists and hospital pharmacists. The target group should be further defined at national level, in agreement with the respective national competent authority. depending on the Member State
Member States where the DHPC will be distributed	Austria; Belgium; Bulgaria; Croatia; Czech Republic; Cyprus; Denmark; Greece; Estonia; Finland; France; Germany; Hungary; Iceland; Ireland; Italy; Latvia; Liechtenstein; Lithuania; Luxembourg; Malta; The Netherlands; Northern Ireland; Norway; Poland; Portugal; Romania; Slovakia; Spain; Sweden

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	2 December 2024
Submission of translated DHPCs to the national competent authorities for review	From 5 December 2024 depending upon release of potential impacted batches
Agreement of translations by national competent authorities	1-3 working days dependent upon respective NCA
Dissemination of DHPC	1-3 working days after final agreement with NCA